UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,054	04/01/2008	Christopher J Soares	0105US-UTL2	5466

44638 7590 05/09/2011

Intellectual Property Department
Amylin Pharmaceuticals, Inc.
9360 Towne Centre Drive
San Diego, CA 92121

EXAMINER	
HOWARD, ZACHARY C	
ART UNIT	**PAPER NUMBER**
1646	

NOTIFICATION DATE	DELIVERY MODE
05/09/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@amylin.com
trademarks@amylin.com

Office Action Summary	Application No.	Applicant(s)	
	10/589,054	SOARES ET AL.	
	Examiner	Art Unit	
	ZACHARY HOWARD	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 March 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-30 and 32-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-30 and 32-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *24-30 and 32-34* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 August 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/23/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments and/or Claims

The amendment of 11/16/10 has been entered in full. Claims 24-26, 30 and 32 are amended. Claims 1-23 and 31 are canceled. New claims 33 and 34 are added.

Claims 24-30 and 32-34 are pending in the instant application.

Election/Restrictions

Applicants' elections of SEQ ID NO: 137 as the species of peptide, and polyethylene glycol (PEG) as the species of polymer, in the reply filed on 1/21/10 were acknowledged at pg 2 of the 5/12/10 Office Action.

In view of Applicants' amendments to the claims, and on further consideration of the claimed species by the Examiner, the first election of species requirement is hereby withdrawn. As such, the non-elected species of peptide (SEQ ID NO: 40, 42, 43, 46-48, 54, 55, 64, 65, 67-70, 73, 74, 78-85, 89-103, 106, 107, 109, 111, 112, 118, 119, 121, 125, 130 and 133) are hereby rejoined and examined for patentability.

The second election of species is maintained for the reasons of record. The pending claims each read on the elected species of PEG.

In view of the above, previously withdrawn claims 25, 28 and 32 are hereby rejoined and examined for patentability.

Claims 24-30 and 32-34 are under consideration, as they read on the elected species.

Information Disclosure Statement

The Information Disclosure Statement of 9/23/10 has been considered.

Sequence Compliance

The Office Action mailed 5/12/10 indicated that the application lacked sequence compliance (i.e., failure to comply with requirements of 37 CFR 1.821 through 1.825), and was accompanied by a PTO-90C and PTO-Notice to Comply. Applicants filed a

response on 11/16/10, which was found persuasive in part. A second PTO-90C and PTO-Notice to Comply were mailed on 2/11/11 indicating why the application still lacked sequence compliance. Applicants' response filed on 2/11/11 has been considered and is found persuasive. The Sequence Listing filed on 3/1/11 contains a SEQ ID NO: 34 that matches SEQ ID NO: 34 in the specification at page 5. Therefore, the requirements set forth in the Office Actions of 5/12/10 and 2/11/11 are withdrawn.

Withdrawn Objections and/or Rejections

The following page numbers refer to the 5/12/10 Office Action.

The objections to the specification at pgs 3-5 are *withdrawn* in view of Applicants' amendments to the specification. However, please see the new objection to the title of the specification necessitated by Applicants' amendments to the claims.

All objections and/or rejections of claims 1-6, 8, 10, 12, 13, 18-20, 22 and 31 are moot in view of Applicants' cancellation of these claims.

The objection to claims 24, 26 and 27 at pg 5 is *withdrawn* in view of Applicants' amendments to independent claims 24 and 26, and the objection to claim 29 at pg 5 is *withdrawn* on further consideration by the examiner. Claim 29 depends from claim 28, which is directed to a peptide having at least 95% sequence identity to the amino acid sequence of SEQ ID NO: 43. Instant SEQ ID NO: 43 and 137 differ by one amino acid and are therefore 97.7% similar (see the alignment provided below in the section titled, "Double Patenting"). Thus, parent claim 28 does encompass SEQ ID NO: 137, and dependent claim 29 does further limit the subject matter of the parent claim.

The rejections of claims 24, 26, 27, 29 and 30 under 35 U.S.C. § 112, first paragraph at pg 7-13 for failing to provide enablement for the full scope of the claims, and at pg 13-15 as failing to comply with the written description requirement are *withdrawn* in view of Applicants' amendments to the claims.

The rejection of claims 24, 26, 27 and 29 at pg 16-18 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent 7,399,744 is *withdrawn* in view of the terminal disclaimer filed by Applicants on 8/9/10 and approved by the USPTO.

New Objections and/or Rejections

Specification

The disclosure is objected to because of the following informalities:

The title of the invention ("AMYLIN FAMILY PEPTIDES AND METHODS FOR USING THEM FOR TREATMENT") is not descriptive because no pending claims are directed to methods. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title is suggested: “AMYLIN FAMILY PEPTIDES”.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 24-30 and 32-34 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 7,671,023 (filed 3/31/06; published 3/2/10). The '023 patent shares three inventors with the instant application (Michael Hanley, Christine Mack and David Parkes). Although the

conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

Instant claims 24 and 26-29 each encompass a peptide having the amino acid sequence of SEQ ID NO: 43. The peptide of SEQ ID NO: 43 differs from SEQ ID NO: 137 by one amino acid, and is therefore 97.7% similar (Qy = SEQ ID NO: 43; Db = SEQ ID NO: 137):

```
  Query Match            97.7%;  Score 169;  DB 5;  Length 32;
  Best Local Similarity   96.9%;
  Matches   31;  Conservative    0;  Mismatches    1;  Indels    0;  Gaps    0;

Qy          1 KCNTATCVLGRLSQELHRLQTYPRTNVGSNTY 32
              |||||||||||||||||||||||||| |||||
Db          1 KCNTATCVLGRLSQELHRLQTYPRTNTGSNTY 32
```

Claims 1-3 of the '023 patent each encompass a method for treating depression in a human in need thereof comprising administering to the human a therapeutically effective amount of an amylin agonist analog comprising the amino acid sequence of SEQ ID NO: 159 to treat depression. SEQ ID NO: 159 of the '023 patent is 100% identical to instant SEQ ID NO: 43 (Qy = SEQ ID NO: 43; Db = SEQ ID NO: 159):

```
  Query Match            100.0%;  Score 173;  DB 3;  Length 32;
  Best Local Similarity   100.0%;
  Matches   32;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy          1 KCNTATCVLGRLSQELHRLQTYPRTNVGSNTY 32
              ||||||||||||||||||||||||||||||||
Db          1 KCNTATCVLGRLSQELHRLQTYPRTNVGSNTY 32
```

No restriction requirement was made in the '023 patent between the product and methods of use thereof. Therefore, the method of use of SEQ ID NO: 159 in the '023 patent anticipates the product claims having the same peptide sequence in the instant application (claims 24 and 26-29).

Instant claims 24-29 and 33 each encompass a peptide having the amino acid sequence of SEQ ID NO: 137. Claims 2 and 3 of the '023 patent also encompass an amylin agonist with the same peptide sequence as instant SEQ ID NO: 137. As described above, SEQ ID NO: 137 is 97.7% similar to SEQ ID NO: 43, and thus falls within the genus of peptides that is 90% or 95% identical to SEQ ID NO: 159 of the '023 patent, as encompassed by claims 2 and 3 of the '023 patent. Furthermore, the portion of the specification that informs the claims indicates that amylin agonists of the invention include SEQ ID NO: 151 (col 21, lines 18-19), which is identical to instant SEQ ID NO:

137. Therefore, claims 2 and 3 of the '023 patent also anticipate claims 24-29 and 33 of the instant application, as directed to the embodiment that is instant SEQ ID NO: 137.

Instant claims 30, 32 and 34 depend from claims 24, 29 and 33, respectively, and encompass a peptide of SEQ ID NO: 43 or 137 that is linked to a polyethylene glycol (PEG) polymer. Claims 1-3 of the '023 patent do not include a peptide of SEQ ID NO: 43 or 137 that is linked to a PEG polymer. However, the portion of the specification that informs the claims indicates that amylin agonists of the invention include those disclosed in PCT/US05/004631 (published as WO 06/083254), which is incorporated by reference (col 10, lines 49-50 of the '023 patent), and which teaches that the amylin agonists can be linked to a PEG polymer (see ¶ 18 on page 8 of the '254 publication). As such, a peptide of SEQ ID NO: 43 or 137 that is linked to a polyethylene glycol (PEG) polymer is taught by the portion of the specification of the '023 patent that informs claims 1-3. Therefore, claims 1-3 of the '023 patent also anticipate claims 30, 32 and 34 of the instant application.

Claims 24-30 and 32-34 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 4-9 and 12-15 of U.S. Patent No. 7,879,794 (filed 3/31/06; published 2/1/11). The '794 patent shares two inventors with the instant application (Christine Mack and David Parkes). Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

Claim 4 of the '794 patent is directed to a method of controlling binge eating in a subject in need thereof comprising administering an effective amount of an amylin agonist to the subject to control binge eating. Claims 5-9 and 12-15 depend from claim 4 and limit the method to particular embodiments each using an amylin agonist.

Claims 5-9 and 12-15 of the '794 patent do not further indicate the structure of the amylin agonist. However, the portion of the specification that informs the claims indicates that amylin agonists of the invention include LHC peptides as disclosed in PCT/US05/004631 (published as WO 06/083254), which is incorporated by reference (col 35, line 55 through col 36, line 12 of the '794 patent), and which teaches peptides

identical to instant SEQ ID NO: 43 and 137 (pg 28-30 of the '254 publication). As such, peptides of SEQ ID NO: 43 and 137 are taught by the portion of the specification of the '794 patent that informs claims 5-9 and 12-15. No restriction requirement was made in the '794 patent between the product and methods of use thereof. Therefore, the method of use of an amylin agonist of claims 5-9 and 12-15, which includes use of the peptides of SEQ ID NO: 43 and 137 anticipates the product claims having the same peptide sequences in the instant application (claims 24-29 and 33).

Instant claims 30, 32 and 34 depend from claims 24, 29 and 33, respectively, and encompass a peptide of SEQ ID NO: 43 or 137 that is linked to a polyethylene glycol (PEG) polymer. Claims 5-9 and 12-15 of the '794 patent do not include a peptide of SEQ ID NO: 43 or 137 that is linked to a PEG polymer. However, the portion of the specification of the '794 patent that informs the claims indicates that amylin agonists of the invention include derivatives conjugated to PEG (col 48, lines 41-42). As such, a peptide of SEQ ID NO: 43 or 137 that is linked to a polyethylene glycol (PEG) polymer is taught by the portion of the specification of the '794 patent that informs claims 5-9 and 12-15. Therefore, claims 5-9 and 12-15 of the '794 patent also anticipate claims 30, 32 and 34 of the instant application.

Claims 24-30 and 32-34 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 20-23 and 26 of copending Application No. 12/641,733 (filed 3/2/2010). The '733 application shares three inventors with the instant application (Michael Hanley, Christine Mack and David Parkes). Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

The claims of the '733 application were amended on 1/6/11, wherein claims 20-23 and 26 are directed to a method of using any amylin agonist selected from a group including SEQ ID NO: 151 (identical to instant SEQ ID NO: 137) and SEQ ID NO: 159 (identical to instant SEQ ID NO: 43). The '733 application is a divisional of application 11/910206, which is issued as U.S. Patent 7,671,023, and therefore shares the same disclosure (specification). Therefore, the methods of the '733 application which uses the

products of SEQ ID NO: 151 and 159 anticipate instant claims 24-30 and 32-34 on the same basis as the '023 patent described above.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 24-30 and 32-34 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 19, 20 and 39-51 of copending Application No. 12/295259 (filed 12/8/08). The '259 application shares all five inventors with the instant application. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

Claims 19, 20 and 39-51 of the '259 application are (as amended 1/27/11) directed to methods of using a peptide of SEQ ID NO: 159, or a peptide that is 90% or 95% similar to SEQ ID NO: 159. SEQ ID NO: 159 of the '259 application is 100% identical to instant SEQ ID NO: 43 (Qy = SEQ ID NO: 43; Db = SEQ ID NO: 159):

```
  Query Match           100.0%;  Score 173;  DB 3;  Length 32;
  Best Local Similarity  100.0%;
  Matches   32;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy          1 KCNTATCVLGRLSQELHRLQTYPRTNVGSNTY 32
              ||||||||||||||||||||||||||||||||
Db          1 KCNTATCVLGRLSQELHRLQTYPRTNVGSNTY 32
```

No restriction requirement was made in the '259 application between the product and methods of use thereof. Therefore, the method of use of SEQ ID NO: 159 in the '259 application anticipates the product claims (claims 24 and 26-29) having the same peptide sequence in the instant application.

Claims 19, 20, 40 and 45-51 of the '259 application also encompass an amylin agonist with the same peptide sequence as instant SEQ ID NO: 137. As described above, SEQ ID NO: 137 is 97.7% similar to SEQ ID NO: 43, and thus falls within the genus of peptides that is 90% or 95% identical to SEQ ID NO: 159 of the '259 application. Furthermore, the portion of the specification that informs the claims indicates that amylin agonists of the invention include SEQ ID NO: 151 (page 30), which is identical to instant SEQ ID NO: 137. Therefore, claims 19, 20, 40 and 45-51 of the '259 application also anticipate claims 24-29 and 33 of the instant application, as directed to the embodiment that is instant SEQ ID NO: 137.

Instant claims 30, 32 and 34 depend from claims 24, 29 and 33, respectively, and encompass a peptide of SEQ ID NO: 43 or 137 that is linked to a polyethylene glycol (PEG) polymer. Claims 19, 20, 40 and 45-51 of the '259 application do not include a peptide of SEQ ID NO: 43 or 137 that is linked to a PEG polymer. However, the portion of the specification that informs the claims indicates that amylin agonists of the invention include those disclosed in PCT/US05/004631 (published as WO 06/083254), which is incorporated by reference (¶ 55 on page 15 of the '259 application), and which teaches that the amylin agonists can be linked to a PEG polymer (see ¶ 18 on page 8 of the '254 publication). As such, a peptide of SEQ ID NO: 43 or 137 that is linked to a polyethylene glycol (PEG) polymer is taught by the portion of the specification of the '259 application that informs claims 1-3. Therefore, claims 19, 20, 40 and 45-51 of the '259 application also anticipate claims 30, 32 and 34 of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 24-30 and 32-34 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4-7, 9-13 and 15-20 of copending Application No. 12/055147 (filed 3/25/08). The '147 application shares one inventor with the instant application (Christine Mack). Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

Instant claims 24-29 and 33 each encompass a peptide of SEQ ID NO: 137. Claims 1, 2, 4-7, 9-13 and 15-20 of the '147 application, as most recently amended on 12/15/10, each encompass a method of use of a peptide of SEQ ID NO: 5.

The following alignment, where Qy is instant SEQ ID NO: 137 and Db is SEQ ID NO: 5 of the '147 application, shows that the two sequences are 100% identical:

```
  Query Match             100.0%;  Score 174;  DB 3;  Length 32;
  Best Local Similarity   100.0%;
  Matches   32;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy          1 KCNTATCVLGRLSQELHRLQTYPRTNTGSNTY 32
              ||||||||||||||||||||||||||||||||
Db          1 KCNTATCVLGRLSQELHRLQTYPRTNTGSNTY 32
```

No restriction requirement was made in the '147 application between the product of SEQ ID NO: 5 and methods of use thereof. Therefore, the method of use of SEQ ID NO: 5 in the '147 application anticipates the product claims in the instant application.

Claims 30, 32 and 34 depend from claims 24, 29 and 33, respectively, and encompass a peptide of SEQ ID NO: 137 that is linked to a polyethylene glycol (PEG) polymer. Claims 1, 2, 4-7, 9-13 and 15-20 of the '147 application do not include a peptide of SEQ ID NO: 5 that is linked to a PEG polymer. However, the portion of the specification of the '147 application that informs the claims indicates that amylin agonists of the invention include derivatives conjugated to PEG (¶ 70 on page 15). As such, a peptide that is identical to SEQ ID NO: 137 that is linked to a polyethylene glycol (PEG) polymer is taught by the portion of the specification of the '147 application that informs claims 1, 2, 4-7, 9-13 and 15-20. Therefore, claims 1, 2, 4-7, 9-13 and 15-20 of the '147 application also anticipate claims 30, 32 and 34 of the instant application.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary C. Howard whose telephone number is 571-272-2877. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Zachary C Howard/
Examiner, Art Unit 1646